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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,141	06/16/2005	Simon Murray Cooper	PG5049USw	2235
23347 7590 07/23/2009 GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B482 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398				
EXAMINER MCKANE, ELIZABETH L.				
ART UNIT 1797		PAPER NUMBER		
NOTIFICATION DATE 07/23/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/539,141

Applicant(s)

COOPER ET AL.

Examiner

ELIZABETH L. MCKANE

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 May 2009 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 11, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Subramaniam et al. (US 6,113,795).

Subramaniam et al. teaches a semi-continuous method for producing a particulate pharmaceutical product. The method of Subramaniam et al. includes providing a non-supercritical liquid solution having a pharmaceutical product dissolved therein which is fed into a particle formation vessel **32** by pump **18**. A supercritical fluid antisolvent **23,21** is provided by pump **20,22** into the particle formation vessel. See Figure 1. The non-supercritical liquid and the supercritical antisolvent are combined at a pressure above the supercritical point of the supercritical fluid, causing precipitation of

the pharmaceutical product. See col.6, lines 1-14. The particulate pharmaceutical product is subsequently isolated from the combined fluids. See col.6, lines 15-31. The step of isolating the pharmaceutical product occurs when the pressure is dropped, converting the CO₂ from a supercritical to a non-supercritical fluid. Thus, the pharmaceutical product is suspended in a non-supercritical fluid. Subramaniam et al. further discloses that the process can be alternatively a continuous process. See col.7, lines 40-42.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Subramaniam et al. in view of Rouanet et al. (US 5,864,923).

Subramaniam et al. teaches an apparatus for the isolation of a particulate pharmaceutical produce from a high pressure process wherein the apparatus includes a particle formation vessel **32** and feed **18** for introducing a non-supercritical liquid solution having a pharmaceutical product dissolved into the vessel, a feed **23,21** for introducing a supercritical fluid antisolvent into the vessel, and a radial filter **56** located within a separation/homogenization vessel **54** for isolation of the particulate pharmaceutical product. See Figure 1. Subramaniam et al. further discloses that the particulate produce is subsequently collected from the vessel **54** but is silent as to how this is accomplished and thus is silent with respect to a valve for controlling transfer of product from the separation vessel and a pressure and temperature controlled collection vessel.

Rouanet et al. discloses a similar apparatus for forming particles using a supercritical fluid. In the apparatus of Rouanet et al. particulate product is formed within a formation vessel **52** and the particulate product separated from the supercritical fluid within vessel **65**. A valve (not shown) is located at the outlet **74** of vessel **65**. Particulate produce is eventually collected in low pressure vessel **76** which is also heated to drive off remaining supercritical fluid. See col.13, lines 13-19. As Rouanet et al. discloses that the combination of the valve and the pressure/temperature controlled vessel **76** is effective in removing the supercritical fluid from the particulate product, it

would have been obvious to use the same in the invention of Subramaniam et al. in order to remove all supercritical fluid from the formed product.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH L. MCKANE whose telephone number is (571)272-1275. The examiner can normally be reached on Mon-Fri; 5:30 a.m. - 2:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/
Primary Examiner, Art Unit 1797

elm
19 July 2009